

July 25, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857-0003

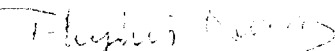
RE: Docket No. 98N-1265

I am writing to express my opposition to the Memorandum of Understanding published by the FDA on January 21, 1999. The MOU, and, in particular, the Compounding Section 503A of the Modernization Act, severely restricts the rights of the physicians and patients to obtain healthcare products from the provider of their choice. As a consumer of healthcare services, I would no longer have access to some compounded drugs that are currently used as effective treatments. The MOU also targets the interstate distribution of compounded prescriptions, with no concern for limiting the same distribution practices for noncompounded prescriptions, further restricting my choice as a consumer.

There is an increasing demand for custom-compounded drugs, many of which use natural ingredients as an alternative to patented synthetics. I, myself, am prescribed a compounded estrogen/progesterone HRT, to counteract excessive bone loss due to menopause. The hormone is derived from plants versus horse urine and has been very effective in helping my body to rebuild bone mass.

It would appear that the drug companies (who already make billions in profits) are concerned that there are drugs in the marketplace that they can't get a piece of. I believe this MOU is meant to threaten the economic survival of specialty pharmacies, and will further restrict consumer choices. I ask that this MOU be revised to adequately address these concerns.

Sincerely,



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